Optibrand™
secure source verification

Date: December 22, 2003

To: Regulatory Analysis and Development, PPD,
            USDA APHIS
            Station 3C71
            4700 River Road Unit 118
            Riverdale, MD 20737-1238

Re: Docket No. 03-080-1

Sir/Madame

We are pleased to submit our comments to the USDA Animal and Plant Health Inspection Service's proposed rule for Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, Docket No. 03-080-1.

Sincerely,

Dr. Bruce Golden
CEO

<u>Optibrand Ltd., LLC Comments on Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, Docket No. 03-080-1</u>

The following presents the comments of Optibrand Ltd., LLC in response to the USDA- Animal and Plant Health Inspection Service's proposed rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, Docket No. 03-080-1.

<u>About Optibrand</u>^{TM}
Founded in 1998, Optibrand Ltd., LLC is based in Fort Collins, Colorado. This company is the originator and supplier of a retinal scanning system for livestock identification and traceability. This system is based on a patented method for combining a biometric identifier for livestock with a Global Positioning System time, place and date reading to provide a unique, tamper resistant record of the location and identity of an animal. Because of our research and expertise we are pleased to be able to present our comments on the critical issues of animal identification, traceability and record keeping.

<u>Livestock Identification and Traceability</u>
Traceback of animals to farms of origin, tracking the movement of animals between farms and markets or abattoirs, and controlling animal movement between countries are critical to animal disease control. Reliable, secure identification and source verification systems clearly make quarantine and containment of animal disease possible. As this proposed rule recognizes, the identity and location of animals are critical factors in determining the risk that importation of these animals into the United States presents to public and animal health.

<u>Identity and Traceability Systems</u>
There are numerous methods available to identify and then trace livestock movements. These include at the most basic level, visual systems using manual record keeping. Hot iron branding, tattoos, and various tagging systems also fall in this category. Electronic and digital methodologies also exist and can be applied to the problem of animal traceability. These include radio frequency identification (RFID) tags, rumenal boluses, and implantable microchips. There are also several biometric methods available for identifying livestock including nose prints, retinal vascular imaging and DNA analysis.

Secure animal identification is the most important issue when tracking livestock from BSE-minimal risk areas. Some animal identification methods such as hot iron branding, tattooing, and visual tagging systems are efficient, but are subject to tampering, tag loss and human error. In addition, hidden costs preclude them from being low cost options. Radio frequency ear tags are another popular solution for animal identification for source verification programs. However, RFID tags do not supply an unalterable solution. They are relatively expensive and prone to loss or falsification. Estimates of between five to eight percent tag loss are not uncommon.

Biometric identifiers are the only secure method that can be used to identify livestock. Woodward et al. (2001)[1] defined a biometric identifier as "any measurable, robust, distinctive physical characteristic …that can be used to identify the claimed identity of the individual.

DNA analysis has been suggested as a biometric method to positively identify animals. While it can be accurate, it is cumbersome and expensive to use. Moreover, systems based on DNA analysis are subject to error or fraud if the "chain" of control between the animal, the sample and the analytical laboratory becomes suspect. DNA analysis does not provide information on animal locations.

Nose prints, another biometric method, are not viable because of the technical challenges associated with collecting non-smudged prints from cattle.

A third biometric identifier is the Retinal Vascular Pattern (RVP). Retinal vascular pattern imaging identifies the animal, not the identifier. All other animal identification systems work on the basis of adding an identifier to the animal, such as a visual or electronic marker and then recording that identifier. Identifiers like this can be lost or changed and are not secure. Some estimates are that tag loss is in the range of 5-8%. Batch or lot identification does not identify the animal, only the group of origin. Only RVP imaging identifies the animal permanently and painlessly by capturing a tamper resistant image of the animal's retinal vascular pattern that is more unique than a human fingerprint. The RVP is present from birth until hours after death and does not change. By linking a Global Positioning System date/time/location to the retinal image, the time, date and location of the animal can be captured when the eye is scanned. This information can then be combined with the retinal image in a secure, encrypted, electronic form, proving beyond doubt that "this animal was at this place at this time."

Research demonstrating that the image of the retina is completely repeatable in the bovine was conducted by Golden (1998)[2]. "Combine the security of using the innate structure of a retina with an encrypted Global Positioning System receiver signal, and it becomes virtually impossible to foil or deceive the system." Whittier et al (2003)[3] demonstrated that the Retinal Vascular Pattern could be used as part of a source-verification process for livestock to provide a humane fraud-resistant tool for many applications in food production from livestock.

Identification of Livestock from BSE minimal risk regions
This proposed rule requires that the slaughter of bovines from BSE minimal risk regions take place under certain restrictions and with different procedures than those used for animals originating in the United States [9 CFR 93.436 (a) (1- 3) i.e. less than 30 months of age, not fed

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[1] Woodward, J.D., K.W. Webb, E.M. Newton, M. Bradley and D. Rubenson. 2001. Biometrics: A Technical Primer. In: Army Biometric Applications – Identifying and Addressing Sociocultural Concerns. Santa Monica: RAND. Appendix A: 67-86.

[2] Golden, B. L. 1998. Retinal Imaging: An un-alterable livestock biometric identification method. In: Proceedings, National Farm Animal Identification Symposium. Nov 8-10, 1998. St. Louis, MO.

[3] Whittier, J.C., J. Doubet, D. Henrickson, J. Cobb, J. Shadduck, and B.L. Golden. Biological Considerations Pertaining to Use of the Retinal Vascular Pattern for Permanent Identification of Livestock. In: Proceedings, Western Section, American Society of Animal Science. Vol. 54, 2003

ruminant protein, and have the intestines remove]. Without a system to securely identify and trace these animals, the USDA would be unable to guarantee that these conditions had been realized.

USDA is proposing to allow the importation of bovines from BSE minimal risk regions into the U.S. under two basic control systems. Animals can be moved without individual identification only if they are moved directly from the port of entry to the slaughter plant. They must be transported under the control of the U.S. government [9 CFR 93.436 (a) (4)] in a conveyance sealed at the port of entry with seals of the United States Government, which are broken at the slaughtering establishment by a USDA representative.

In this rule, the Agency recognizes that when animals are to be contained in a feedlot for some period of time prior to slaughter, the risk of loosing track of any individual animal increases. Obviously this risk is unacceptable given the more restrictive harvesting requirements for these animals. Therefore, the rule will require that all bovines be identified with a tattoo on the inside of one ear indicating the exporting country. For Canada this would be the letters "CAN". (Note that these same basic requirements would be applied to the importation of sheep or goats from BSE-minimal regions.)

We agree with the USDA's rationale for identification and tracking of livestock and believe that only secure, tamper resistant systems should be allowed for this purpose. Hot brands, visual tags, or electronic or radio-frequency tags are subject to loss and tampering and thus cannot provide the security needed to protect public and animal health. However, we believe that the USDA has mandated the use of tattoos under the mistaken belief that this is the only secure, tamper resistant method both acceptable and available for identifying and tracing livestock from BSE minimal risk regions.

Furthermore, in requiring the use of tattoos, USDA is limiting compliance to one archaic technology. This will, in effect, result in the U.S. government sanctioning one specific portion of the animal identification industry and keeping other acceptable technologies out.

USDA should not limit the use of acceptable technologies to identify animals from BSE minimal risk regions. Instead, USDA should establish standards for animal identification and traceability systems. At a minimum, such standards should address the maximum permissible probability that an acceptable animal identification and traceability system might loose track of an animal. This will provide the industry with the information it needs to develop technologies that meet the needs of USDA for tracking animals from BSE minimal risk regions.

Retinal Vascular Imaging
There is at least one other existing technology, retinal vascular pattern imaging, that meets the USDA's requirements for a secure tamper resistant method for identifying livestock from BSE minimal risk regions. Furthermore, because retinal vascular pattern imaging systems are electronic, their use can assist USDA in achieving compliance with the Government Paperwork Reduction Act, which requires the consideration of electronic options for submitting information or transacting business.

We urge the USDA to allow the use of retinal vascular imaging systems for identifying, tracing and documenting the importation of livestock from BSE minimal risk regions. Retinal vascular pattern imaging is an example of a secure, tamper resistant system that meets the Agency's security requirements. It is based on a unique biometric animal identifier, which when combined with Global Positioning System capabilities, allows animal traceability across location, date and time.